Zagallo Capsules Drug Use Investigation (202029)

First published: 08/03/2016

Last updated: 18/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12703

Study ID

48259

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This investigation will be implemented to collect and evaluate the information on safety and effectiveness of Zagallo Capsules in male patients with androgenetic alopecia in daily clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 800 centres are involved in the study

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/09/2014

Study start date
Planned: 30/03/2016

Actual: 22/07/2016

Date of final study report
Planned: 30/09/2019

Actual: 13/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-202029-protocol-redact.pdf(177.07 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

This investigation is implemented to collect and evaluate the information on safety and effectiveness of Zagallo Capsules in male patients with androgenetic alopecia in daily clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational post-marketing surveillance

Study drug and medical condition

Name of medicine, other

zagallo capsules

Medical condition to be studied

Androgenetic alopecia

Population studied

Short description of the study population

Male patients aged 18 years or older diagnosed with androgenetic alopecia (AGA) receiving Zagallo for the first time for hair growth, hair restoration and prevention of hair loss under routine clinical practice from May 2016 to January 2019.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Other

Renal impaired

Special population of interest, other

Patients with androgenetic alopecia

Estimated number of subjects

4000

Study design details

Outcomes

Information regarding the safety and efficacy of Zagallo Capsules under the actual post-marketing use conditions of the product.

Data analysis plan

Patient disposition ADR related itemsResponse rate based on the global assessment of effectivenessFactors considered influential on safety and effectiveness, odds ratio and 95% confidence interval thereof shall be calculated for the factors considered influential.

Documents

Study results

gsk-202029-clinical-study-report-redact.pdf(975.57 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No